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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,563	09/26/2003	Gerhardt Kumpe	06478.1494	8137

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EXAMINER

ROOKE, AGNES BEATA

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/670,563

Applicant(s)

KUMPE ET AL

Examiner

Agnes B. Rooke

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 July 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 and 16-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>02/11/04; 09/26/03</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's election with traverse of Group II, Claims 10-15 in the reply filed on July 13, 2005 is acknowledged. The traversal is on the ground(s) that the search can be made without undue burden because literature search for Groups I-III would be largely coextensive, and that Groups II and III involve subject matter that has been given the same classification.

Examiner respectfully disagrees, since Group I refers to a concentrate, and Groups II and III refer to different methods of producing the concentrate.

Therefore, the restriction requirement is deemed proper and is made FINAL.

Claims 1-18 are pending.

Claims 1-9 and 16-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected invention.

10-15 are currently under examination.

A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP paragraph 821.01.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter,

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 10 states that any amino acid and/or any metal salt can be used in the process. Also, claim 10 refers to a genus of amino acids and a genus of alkali metals, where claim 11 refers only to one specie of glycine, and claim 12 refers only to one specie of NaCl.

Claim 11 requires glycine combined with any alkali metal, and claim 12 requires NaCl with any amino acid.

Claims 13 and 14 require any amino acid and any alkali metal.

Claim 15 does not refer to any physical and chemical conditions for the stabilization and pasteurization of the concentrate or the concentrate precursor. Therefore, the written description requirement for claims 10-15 is not satisfied.

Claims 10-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing a concentrate of VIII:C containing von Willebrand factors comprising subjecting a liquid comprising factor VIII:C and Willebrand factor to fractional precipitation using glycine and NaCl wherein the fractional concentration of glycine is 70-160 g/l and the fractional concentration of NaCl is 100-160 g/l, and does not reasonably provide enablement for all amino acids and all metal salts. The specification does not enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The specification does not enable a person skilled in the art to which it pertains, or with which it is mostly connected, to make or use the invention commensurate in scope with these claims. In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described. They are: 1) the nature of the invention, 2) the breadth of the claims, 3) the state of the prior art, 4) the predictability or lack thereof in the art, 5) the amount of direction or guidance present, 6) the presence or absence of working examples, 7) the quantity of experimentation needed, and 8) the level of the skill in the art.

1) the nature of the invention: the invention is a process for producing a concentrate of a factor VIII:C containing von Willebrand factor by fractional precipitation using amino acids and metal salt;

2) the breadth of the claims: claims are broad (See claims 10-15) because they claim any amino acid and/or any metal salt that can be used in the process;

3) the state of the prior art: the prior art discloses a similar method where glycine and NaCl are used in the process;

4) the predictability or unpredictability of the art: Claims 10, 13, and 14, and 15 state that any amino acid and any alkali or alkaline metal salt could be used in the method, and therefore, there could be many potential candidates of amino acids or metals, which are used in the method. Thus, the art is unpredictable, since undue

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experimentation would be necessary to characterize all possible amino acids and metals; claim 11 requires glycine combined with any alkali metal and claim 12 requires NaCl with any amino acid;

6) the presence or absence of working examples: the disclosure identifies only glycine and NaCl that are used in the instant method;

7) the quantity of experimentation necessary: there would be an undue experimentation necessary to determine, and characterize all possible amino acids and metal salts that could be used in the method;

8) the relative skill of those skilled in the art: the skill in the art is high, since similar method, which uses glycine and NaCl is known in the art.

In consideration of the *In re Wands* factors 1-8, it is apparent that there is undue experimentation necessary because of variability in prediction of the outcome that is not addressed by the present application disclosure, example, teachings, and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue, rendering claim 10 and its dependent claims 11-15 subject to scope of enablement rejection.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 10-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 10, the full names of "vWF:RcoF" and "vWF:Ag" must be spelled out. Also, the claim is indefinite because it is not clear what is the max value for the ratio "*greater than 1.*"

In Claim 14, the full spelling of the name of "RcoF" must be provided. Further, the terms "preferential precipitation" at "lower concentration" or "higher concentrations" are indefinite. Also, the words expressing "higher" and "lower" concentrations or molecular weight multimers, are indefinite, since no range of values is provided. Therefore, the claim is indefinite.

In Claim 15, the "*concentrate precursor*" is indefinite, since the structure or name of the precursor is not provided in the claim, and the claim lacks antecedent basis to claim 10; also it is not clear how the process is stabilized and pasteurized (for example, claim lacks a temperature range, pH, and most appropriate time frame is missing from the claim.

Claims 11-13 are included in this rejection because they depend from rejected independent claim 10.

#### ***Relevant prior art of record***

The U.S. 6,239,261 describes in Claims 1-3 and 7, a process of preparation von Willebrand factor concentrate; where the FVIIIc binds to an anion exchanger and the

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von Willebrand factor concentrate is free from FVIII:C; where von Willebrand concentrate is treated with glycine to precipitate proteins; where NaCl is added to precipitate von Willebrand factor; and in Claim 7 it states that solution of von Willebrand factor is pasteurized. The reference is not 35 U.S.C. 103a) rejection because it does not specify the ratio of vWF:RcoF activity to vWF:Ag of greater than 1 in a concentrate of factor VIII:C and von Willebrand factor.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see <http://pair-direct.uspto.gov>. or call 866-217-9197.

AR

*12/10/11*  
MARYAM MONSHIPOURI, PH.D.  
PRIMARY EXAMINER